Section 5: 510(k) Summary

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Kimberly A Nemeth, Ph.D. Regulatory Affairs Manager (513) 634-3768 (voice) (513) 277-7085 (fax)
Date Summary Prepared:	May 27, 2010
Trade Name:	TAMPAX® Pearl Plastic Applicator Unscented Tampons
Common Name:	Unscented Menstrual Tampon
Classification Name:	Unscented Menstrual Tampon (21 CFR 884.5470)
Predicate Devices:	TAMPAX® Pearl Plastic Applicator Unscented Tampons - Light, Regular, Super, and Super Plus (K011996) TAMPAX® Pearl Plastic Applicator Unscented Tampons – Ultra (K051290)

JUN - 1 2010

Device Description: The device is a conventional unscented menstrual tampon consisting of an absorbent pledget, an overwrap, a withdrawal cord, an absorbent braid, and an applicator.

Intended Use: This device is intended to be inserted into the vagina to absorb menstrual fluid.

Technological Characteristics: This device is similar to the predicate devices in terms of component materials, overall design, intended use, and labeling. The 510(k) device incorporates a process aid to substantially decrease the microwave time needed to set the pledget.

Non-Clinical and Clinical Testing: Preclinical and clinical toxicology information was gathered and evaluated in accordance with FDA guidance and applicable standards, including irritation testing, sensitization testing, acute toxicity and cytotoxicity testing. In the clinical trials that were performed, no adverse events related to the test products were reported.

Preclinical microbiology testing confirmed that the 510(k) device does not impact the growth of *Staphylococcus aureus* or the normal vaginal microflora, nor does it increase the production of TSST-1.

The favorable safety outcomes associated with the preclinical toxicology testing, preclinical microbiology testing, and clinical evaluations support the conclusion that this 510(k) device is equally as safe as the predicate devices.

Effectiveness: TAMPAX® Pearl Plastic Applicator Unscented Tampons comply with the syngyna absorbency requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampons in terms of effectiveness.

Conclusions: The results of evaluations of this device support the conclusions that it is safe for its intended use and that it is substantially equivalent to the cited predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Kimberly A. Nemeth, Ph.D.
Regulatory Affairs Manager
Proctor & Gamble Co.
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CINCINNATI OH 45224

JUN - 1 2010

Re: K091281
Trade Name: Tampax Pearl Unscented Menstrual Tampons
Regulation Number: 21 CFR §884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HFB
Dated: May 21, 2010
Received: May 21, 2010

Dear Dr. Nemeth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K091281

Device Name: TAMPAX® Pearl Plastic Applicator Unscented Tampons

Indications for Use:

TAMPAX® Pearl Plastic Applicator Unscented Tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091281